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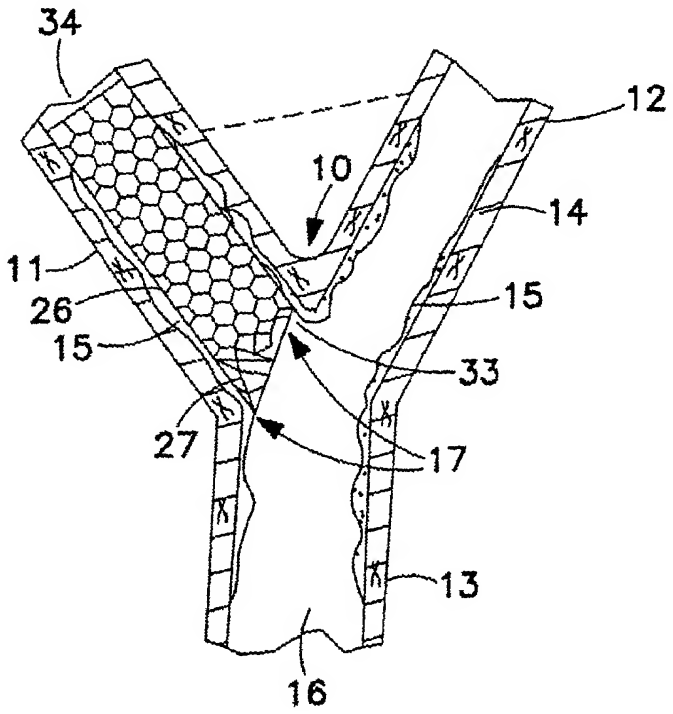
(54) Title: ANGULAR VASCULAR STENT



(57) Abstract: This invention is a method, and device for treating one or more vessels at a bifurcation (10) without blocking or restricting the flow of blood; an expandable and deformable stent (25) having a cylindrical body; and an angled portion (27) at one or both ends. The angled stent (25) is located, and oriented at the bifurcation (10) so that when expanded the cylindrical body and the angled proximal end (27) fully support the first vessel without compromising or interfering with the second vessel. One or more of such angled stent (25) may be deployed at a bifurcation (10).

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

ANGULAR VASCULAR STENT

FIELD OF THE INVENTION

The present invention relates to stent to be used in a bifurcating vessel, and, more particularly, to an expandable and deformable stent having a cylindrical body and an angled portion at one or both ends and a method for using same.

BACKGROUND OF THE INVENTION

A stent is used for treating occlusions, stenoses, or aneurysms in a blood vessel. Typically, the stent is compressed and implanted in a blood vessel, artery or vein, at the site of the stenosis or other restriction to reinforce and support collapsing, occluded or weakened sections of the vessel. Once in position in the blood vessel, the stent is expanded, dilating the vessel at the site and enabling the blood to flow more freely through the vessel.

While generally satisfactory for the treatment of sites in continuous or unbifurcated portions of the vessels, arteries or veins, prior art stents are not well suited where the site of the desired treatment is located at or across a bifurcation. One of the difficulties with conventional stents is that they are produced in a straight tubular configuration, employing features with "squared off ends". The implantation of the conventional stent in one branch at or near a bifurcation can result in either positioning a portion of one end of the stent extending into or across the bifurcation thereby obstructing or compromising the other branch and/or the bifurcation, restricting the blood flow and leading to an unfavorable result. On the other hand, by locating the other end of the stent sufficiently away from the bifurcation so as not to interfere with or obstruct the other branch, the damaged or diseased bifurcating vessel is not fully treated.

U.S.Patent No. 4,994,071 discloses a bifurcating stent which includes a structure, particularly a series of interconnected loops defining a first flow path and an additional structure, using a second series of interconnected loops defining a second branching flow path. An interconnection joins the structures that define the first and second flow paths which is then bent to conform to the shape of the vessel.

U.S. Patent No. 5,607,444 discloses an expandable stent which is constituted of a tubular member having and portion that is flared. The stent is placed within the bifurcated vessel to be repaired with the flared portion extending beyond the junction

of the bifurcation and into the other branch. The flared portion is then "capped" or folded back along the wall of the other branch at the bifurcation.

U.S. Patent No. 5,938,696 discloses stents for use at a bifurcation comprised of a first stent including a proximal engaging portion which may be flared and a second stent providing a cooperating portion to accept the engaging portion. In use at least one of the stents extends across the bifurcation into another branch vessel.

However, the prior art stents do not satisfactorily correct the stenosis at the bifurcation. In order to overcome these problems, a stent that will expand in juxtaposition with a bifurcation, treating the entire damaged or diseased vessel and without extending into the bifurcation or overlapping into the other branch, without restricting or blocking the pathway or risking damage to the bifurcation and other branch is needed.

SUMMARY OF THE INVENTION

The present invention is directed to an angled stent device for treating one or more vessels at a bifurcation without blocking or restricting access or blood flow to the bifurcation or other vessels. The invention also provides a method for using the stent.

The stent is comprised of an expandable cylindrical portion and an angled portion at one or both ends. The stent is constructed of a material capable of radial expansion and having sufficient strength to retain its shape after expansion and to support the most proximal end of the angled portion. In the preferred embodiment, the cylindrical portion has a symmetrical geometric pattern which facilitates the expansion while providing the required strength. The angled portion of the stent extends from the cylindrical portion, the angled portion being configured at an angle substantially approximating the angle established at the bifurcation by the junction of the bifurcated vessel and the other branch, once expanded. The expansion of the angled portion at or near the bifurcation is consistent with the expansion of the cylindrical portion. Preferably, the angled portion has an asymmetrical geometric pattern and is constructed of the same material as the cylindrical portion. Alternatively, the angled portion may be constructed of a different material or may be implanted apart from the cylindrical portion.

A preferred use of the angled stent is accomplished by means of a balloon catheter. The stent is arranged coaxially on the balloon with the angled portion on the proximal portion of the balloon and the cylindrical portion on the distal portion of the balloon. Alternatively, depending upon the introduction of the stent at the bifurcation, these position can be reversed. The balloon-stent assembly is arranged on the catheter and is advanced to the location of treatment within the vessel. In the preferred embodiment, a radio-opaque marker is arranged on one end of the balloon adjacent to the angled portion of the stent. A buttress or stop cap is arranged on the on the distal end of the balloon to retain the stent in position on the balloon. The desired location and orientation of the balloon-stent assembly is achieved by means of radiography. Once the balloon-stent assembly is in position, the balloon is expanded, deploying the expanded stent within the vessel such that of the angled portion is in juxtaposition with the bifurcation and together with the cylindrical portion fully supports the damaged or diseased portion of the bifurcated vessel without extending across or into the bifurcation or the other vessel. Following deployment of the stent, the balloon is deflated and the balloon, radio-opaque marker, stop cap and catheter are removed from the patient.

It will be appreciated that a stent according to the invention would have the advantage of fully treating the damaged or diseased vessel at or near the bifurcation without compromising or obstructing the blood flow in other portions of the bifurcation. A further advantage is that such stent will allow access to and will not interfere with any treatment introduced or delivered to the bifurcation or other vessel. Another advantage of a stent according to the invention is that such stents, having the same or different angles or shapes, or combination of angles or shapes, for example frustoconical, at one end may be used in more than one branch at a bifurcation without extending into, obstructing or compromising the bifurcation, and without overlapping an adjacent branch or stent.

These and other objects, features and advantages of the present invention will be better understood with reference to the detailed description of the preferred embodiment and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1a and 1b show conventional stent devices of the prior art in an expanded configuration at a bifurcation;

FIG. 2 is a side view of one embodiment of the angled stent device of the present invention in an unexpanded configuration;

FIG. 3 is a side view of the unexpanded angled stent according to the present invention arranged on a balloon catheter;

FIG. 4 shows a side view of the unexpanded angled stent of FIGS. 2 and 3, illustrating a preferred method of placement of the stent at a bifurcation;

FIG. 5 shows one embodiment of the angled stent device of the present invention in an expanded configuration;

FIGS. 6 and 7 are side views of alternative embodiments of the present invention;

FIG. 8 shows another embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention includes a device and method for treating one or more vessels at a bifurcation without blocking or restricting access or blood flow to the bifurcation or other vessels.

As shown in FIGS. 1a and 1b conventional stents 5 are produced in a straight tubular configuration having squared off ends 3. FIG. 1a depicts conventional stent 5 in its expanded form, implanted in a bifurcated vessel 11 at or near a bifurcation 10 opening up the restriction to interior arterial passage 16 caused by stenosis 15 and providing support for the vascular wall 14. By attempting to fully treat the diseased or damaged vessel 11, proximal end 33 of conventional stent 5 extends into the bifurcation 10 and junction 17 thereby obstructing branches 12, 13, restricting the blood flow. FIG. 1b shows prior art stent 5 after expansion, positioned in bifurcated vessel 11 with the end 33 sufficiently remote from the bifurcation 10 and junction 17 so as not to extend into the bifurcation. However, the damaged or diseased bifurcated vessel 11 is not fully treated as the stent 5 does not reach portions of junction 17 of the bifurcation.

An angular stent 25 according to the present invention which is depicted in FIG. 2 provides for the complete treatment of a diseased or damaged bifurcated vessel without obstructing the bifurcation.

As shown in FIG. 2, angular stent 25 is comprised of expandable cylindrical portion 26 and expandable angled portion 27 at the proximal end 33. Preferably, the angular stent 25 is constructed of a material capable of radial expansion and having sufficient strength to retain its shape after expansion and to support the most proximal end of the angled portion 27. In the preferred embodiment, the cylindrical portion 26 has a symmetrical geometric pattern which facilitates the expansion while providing the required strength. The angled portion 27 of stent 25 extends from cylindrical portion 26, substantially parallel to longitudinal axis 28, end 33 of the angled portion 27 being configured at an angle substantially approximating the angle established at the bifurcation 10 by the junction 17 of the bifurcated vessel 11 and the other branches 12, 13, once expanded. The expansion of the angled portion 27 at or near the bifurcation 10 is consistent with the expansion of the cylindrical portion 26 of the stent. Advantageously, the stent may be produced having any angle or combination of angles at one or both ends. Accordingly, the stent and or angled portion of the stent best approximating the angle established by the junction of the vessel or vessels to be treated and the other branch or branches of the bifurcation may be selected for implantation.

Preferably, the angled portion 27 has an asymmetrical geometric pattern and is constructed of the same material as the cylindrical portion 26. Alternatively, the angled portion may be constructed of a different material or may be implanted apart from the cylindrical portion.

A preferred use of the angled stent 25 according to the invention is accomplished by means of a balloon catheter 35. Unexpanded stent 25 is arranged coaxially on balloon 32 with the angled portion 27 at end 33 portion of the balloon 32 and the cylindrical portion 26 of the stent 25 at the distal portion 34 of the balloon. Tubular portion 36 extends from the end of balloon 32 as a conduit allowing for inflation and deflation. Guide wire 29 extends the length tubular portion 36 and balloon 32. In the preferred embodiment, expandable radio-opaque marker 30 is arranged at the end 33 of the balloon 32 adjacent to the angled portion 27 of the stent

25, the adjacent end of the marker 30' being angled correspondent to the end of angled portion of the stent. Proximal angular stop 30' may be arranged on balloon 32 between the end of the angled portion 27 and the radio-opaque marker 30' to maintain the alignment and positioning of the stent 25 on the balloon catheter 35. A buttress or stop cap 31,which may also be radio-opaque, is arranged on the on the distal end 34 of the balloon 32 to retain the stent 25 in position on the balloon. Further, the radio-opaque marker 30' and buttress or stop cap 31 enable the physician or radiographer to observe the placement and orientation of the stent and balloon catheter assembly within the arterial passageway and the bifurcated vessel.

As shown in FIG. 4, the unexpanded stent 25 and balloon catheter 35 assembly is advanced, for example, through interior arterial passageway 16, to the intended location of treatment within the bifurcated vessel 11. By use of radiography, the radio-opaque marker 30' and the stop cap 31 are observed and the unexpanded angular stent 25 is advanced into the desired position within the bifurcated vessel 11. Once the stent 25 is in position balloon 32 is expanded, deploying the expanded angular stent 25 within the vessel 11 such that the end 33 of the angled portion 27 of the stent is in juxtaposition with junction 17 of bifurcation 10 and together with the cylindrical portion 26 fully supports the damaged or diseased portion of the bifurcated vessel 11 without extending across or into the bifurcation 10 or the other vessels 12, 13. Following expansion and deployment of the stent, the balloon is deflated and the balloon, radio-opaque marker, stop cap and catheter are removed from the patient, as shown in FIG. 5. In this way diseased or damaged vessel 11 is completely treated and blood flow is not obstructed or restricted by any portion of the stent or overlapping, allowing access for any treatment introduced or delivered to the bifurcation or other vessels without interference. Alternatively, depending upon the introduction of the stent to the bifurcation 10, the arrangement of the stent, the radio-opaque marker and the stop cap on the balloon catheter may be reversed.

Another embodiment of the present invention is the use of angular stents in two branches of the bifurcation. FIG. 6 shows a dual stent application in accordance with the invention. Similar to the implantation of angled stent 25 in the bifurcated vessel 11 as depicted in FIGS. 3 and 4, the angular stents in a dual application may completely treat the diseased or damaged sites without interfering with or overlapping

the other stent and without extending into the bifurcation or otherwise obstructing or restricting the blood flow.

FIG. 7 depicts another embodiment, an angular stent 25 according to the invention, after expansion is in position in the bifurcated vessel 11 and a conventional stent 5, is implanted in the bifurcation. In this way the bifurcation is treated and the stents are not compromised.

In another embodiment, an example of additional or subsequent treatment to a repaired bifurcation area is shown. FIG. 8 shows dual angular stents 25 implanted and deployed in branches 11 and 12. Stent 25' including an angled portion 27 having a frustoconical configuration 40 is implanted in other branch 13. Although the end 40 of the angled portion of stent 25' extends into the bifurcation, as a result of the configuration of the angled stents the diseased or damages vessels are completely treated without any such stent obstructing or compromising the bifurcation or overlapping an adjacent branch or stent.

It will be appreciated that the angular stent according to the invention enable full treatment of the damaged or diseased vessel at or near the bifurcation without compromising or obstructing the blood flow in other portions of the bifurcation vessel. It will also be appreciated that the angular stent according to the invention may be produced having a variety of angles or combination of angles or shapes, and may be used in more than one branch at a bifurcation without extending into, obstructing or compromising the bifurcation, and without overlapping an adjacent branch or stent.

Although described in terms of the presently preferred embodiment, those skilled in the art will appreciate that the present invention is not limited to the embodiment described.

CLAIMS

1. A stent comprising, a cylindrical portion having two ends wherein at least one said end having an angled portion forming an angle with respect to a longitudinal axis of said cylindrical portion.

2. A stent as claimed in claim 1, wherein said cylindrical portion and said angled portion being expandable in a radial direction about said longitudinal axis,

3. A stent as claimed in claim 1, wherein said angle approximating an angle established at a bifurcation by a junction of two or more bifurcated vessels.

4 A stent as claimed in claim 1, wherein said cylindrical portion and said angled portion are constructed of a flexible material capable of radial expansion, said material having sufficient strength to retain its shape after expansion and to support the most proximal end of the angled portion.

5. A stent as claimed in claim 1, wherein the cylindrical portion is symmetrical about said longitudinal axis

6. A stent as claimed in claim 1, wherein said angled portion expands consistently with the expansion of the cylindrical portion.

7. A stent as claimed in claim 1, wherein the angled portion is constructed of the same material as the cylindrical portion and formed as a single unit.

8. A stent as claimed in claim 1, wherein the angled portion is constructed of a different material than the cylindrical portion.

9. A method for using an angular stent, comprising the steps of:

arranging an unexpanded stent having a cylindrical portion and an angular portion coaxially on a balloon catheter, the balloon having tubular portion and two end portions;

arranging the cylindrical portion of the stent is on the tubular portion of the balloon;

arranging the angled portion of the stent at an end portion of the balloon,

arranging an expandable marker on one end of the balloon adjacent to said angled portion and;

arranging an expandable stop cap on the other end portion of the balloon.

10. The method of claim 9, further comprising the step of advancing the unexpanded stent and balloon catheter to an intended location in a vessel and positioning said stent by observing the expandable marker and the stop cap.

11. The method of claim 9, further comprising the step of expanding the balloon and deploying the expanded angular stent such that the end of the angled portion of the stent is in juxtaposition with a junction of a bifurcation.

12. The method of claim 9, further comprising the step of deflating the balloon and removing the balloon, expandable marker, expandable stop cap and catheter are from the patient.

13. The method of claim 9, wherein the expandable marker and/or the expandable stop cap are radio-opaque.

14. The method of claim 9, wherein the expandable marker is arranged on the end portion of the balloon.

15. The method of claim 9, wherein the adjacent end of the expandable marker is angled correspondent to the end of angled portion of the stent.

16. The method of claim 9, wherein the expandable marker is arranged on the distal end portion of the balloon.

17. The method of claim 9, wherein the adjacent end of the expandable marker is angled with respect to the distal end of angled portion of the stent.

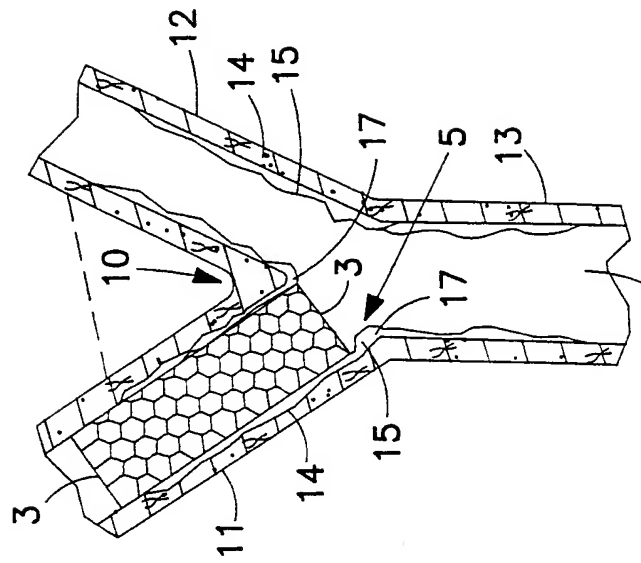

FIG. Ib
PRIOR ART

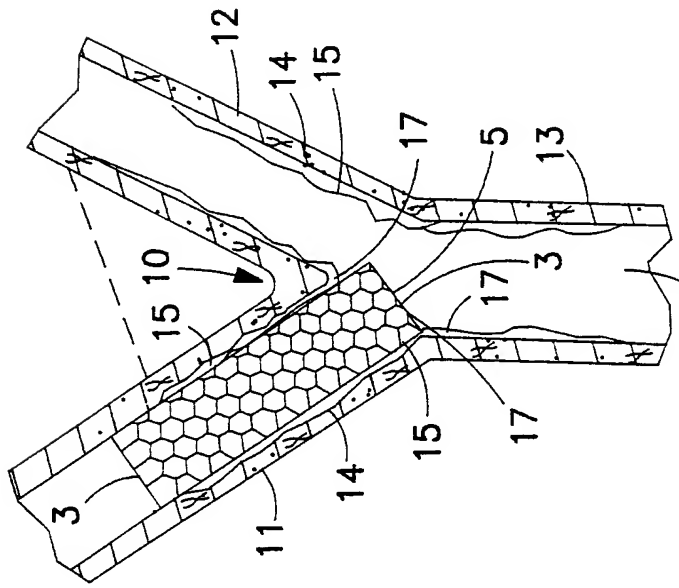

FIG. Ia
PRIOR ART

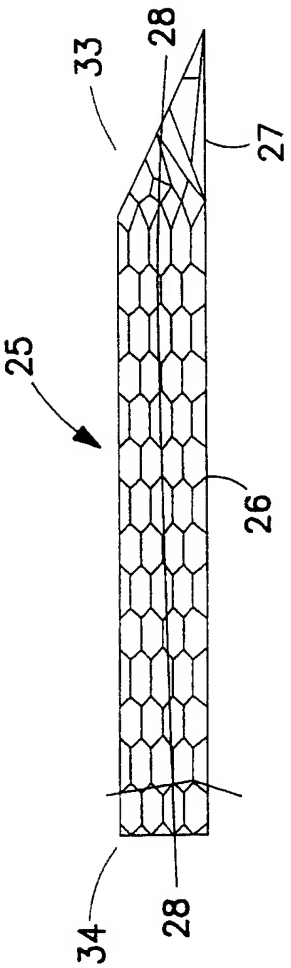

FIG. 2

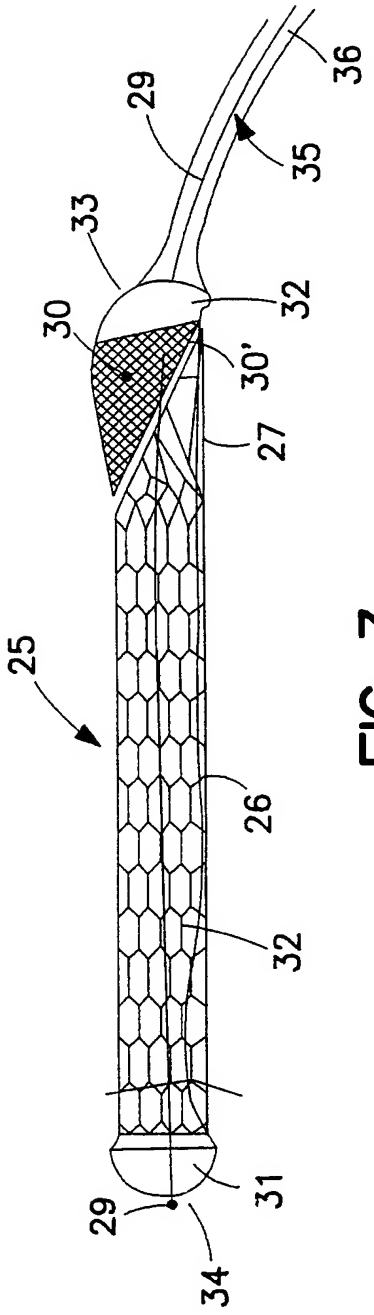

FIG. 3

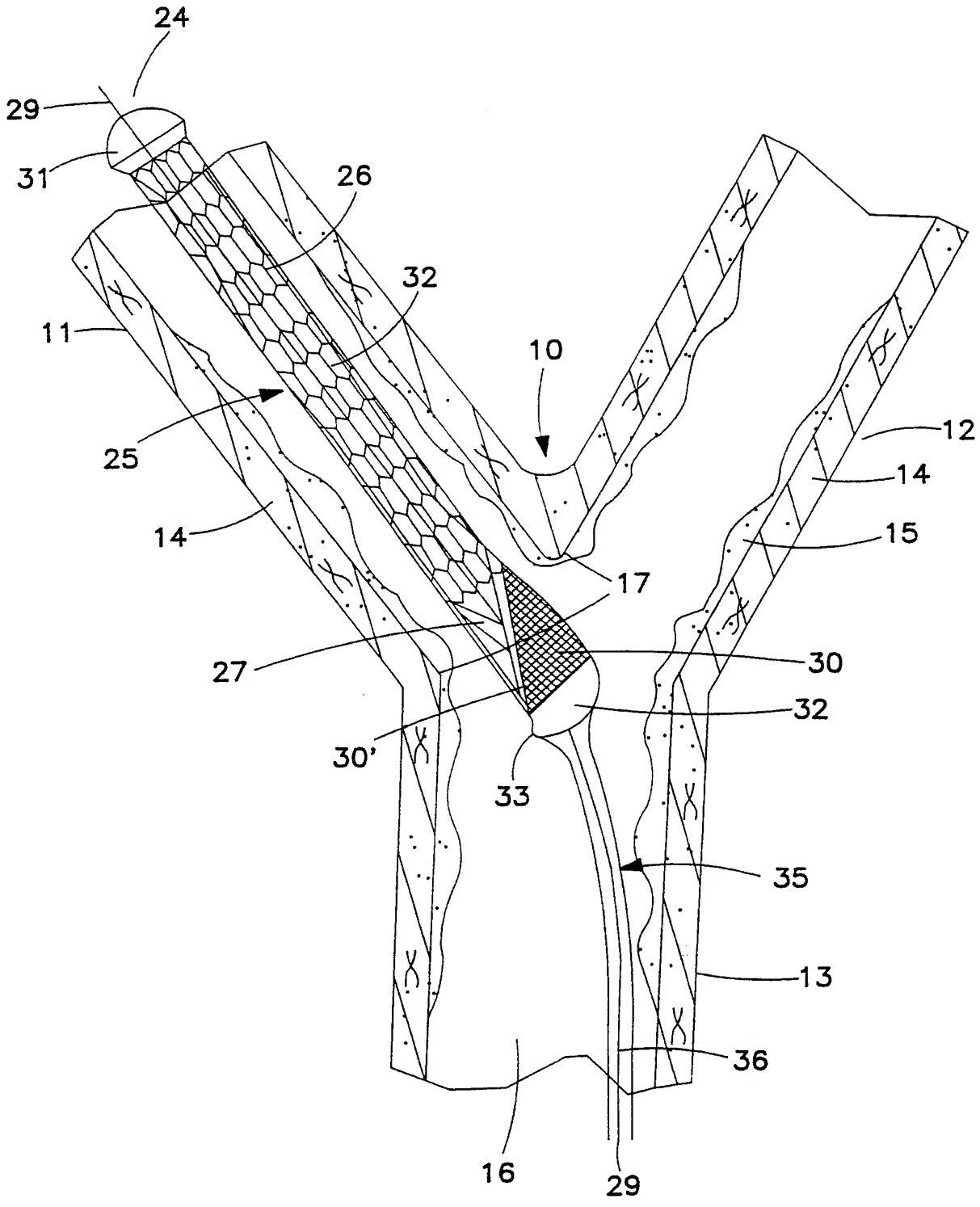

FIG. 4

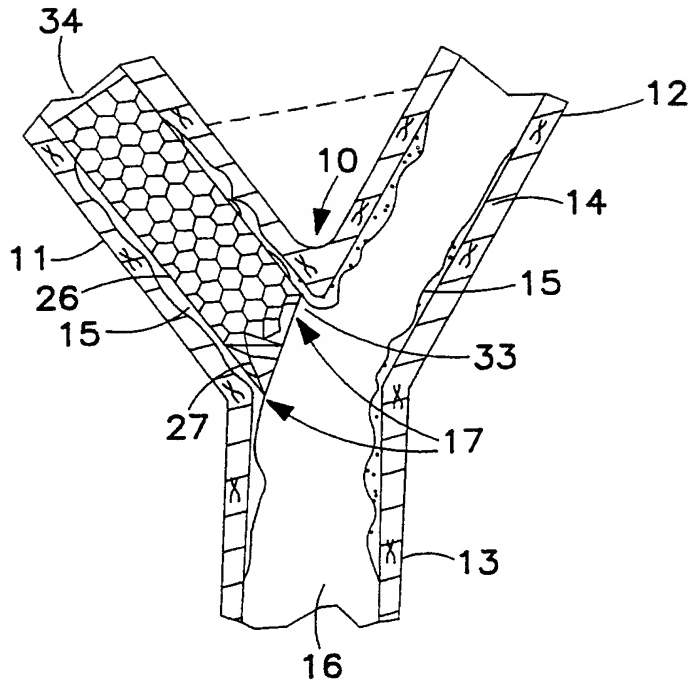
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FIG. 5

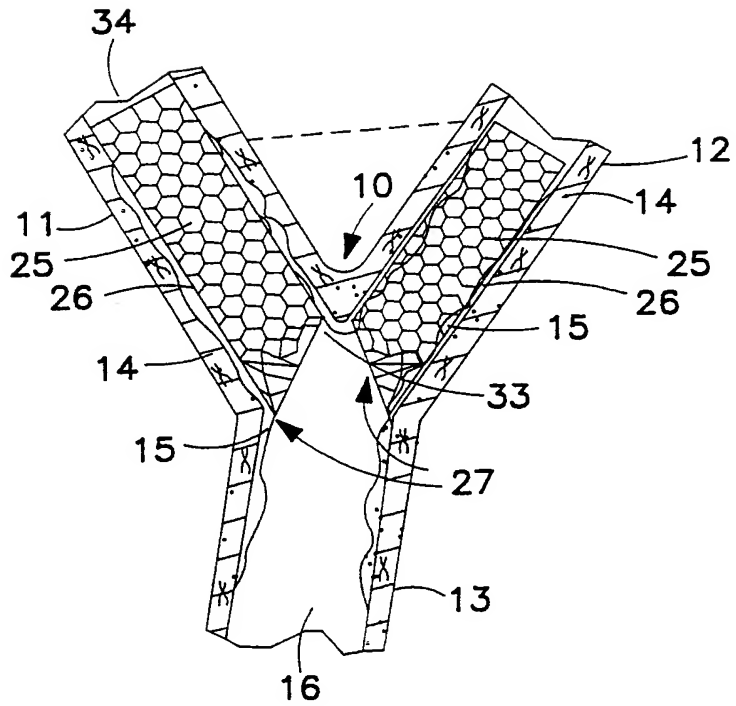
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FIG. 6

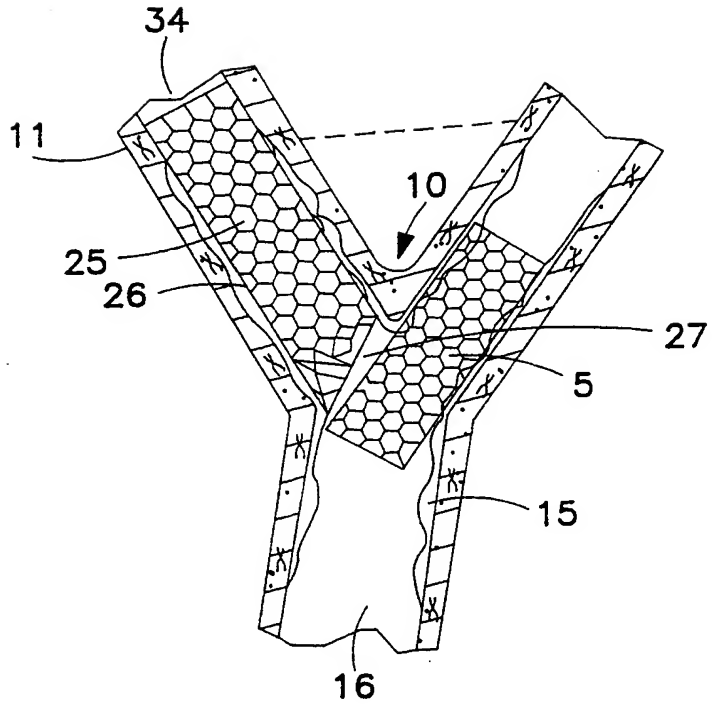
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FIG. 7

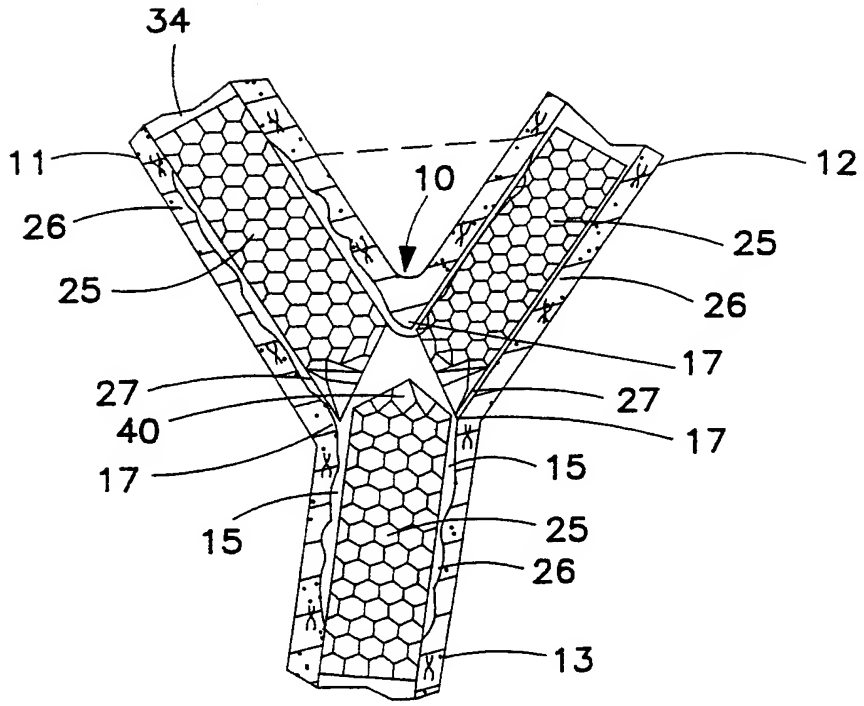
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FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/08482

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) :A61F 2/00
US CL :623/1
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 623/1, 11, 12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A, P	US 5,893,887 A (JAYARAMAN) 13 April 1999, entire document.	1-17
A, P	US 5,906,640 A (PENN et al.) 25 May 1999, entire document.	1-17

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 01 JUNE 2000	Date of mailing of the international search report 27 JUN 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer MICHAEL MILANO Telephone No. (703) 308-2496

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